IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P. and GRÜNENTHAL GMBH Plaintiffs, v. WATSON LABORATORIES, INC. – FLORIDA, and ANDRX LABS, LLC, Defendant.	Case No. 1:13-CV-0762 ECF CASE

ANSWER AND COUNTERCLAIMS OF DEFENDANTS WATSON LABORATORIES, INC. – FLORIDA AND ANDRX LABS, LLLC

Defendants Watson Laboratories, Inc. – Florida ("Watson") and Andrx Labs, LLC ("Andrx") (collectively, "Defendants") hereby answer the complaint of Plaintiffs Purdue Pharma L.P. ("Purdue") and Grünenthal GmbH ("Grünenthal") (collectively, "Plaintiffs") as follows:

NATURE OF THE ACTION

1. Defendants admit that Plaintiffs purport to state claims that arise under the patent laws of the United States. Otherwise denied.

THE PARTIES: PLAINTIFFS

2. Upon information and belief, Defendants admit that Purdue is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901. Upon information and belief, Defendants also admit that Purdue is the holder of NDA No. 022272, which relates to controlled-release oxycodone hydrochloride tablets, and that Purdue sells its controlled-release oxycodone hydrochloride tablets under the trade name OxyContin.

Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

3. Upon information and belief, Defendants admit that Grünenthal is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstaβe 6, North Rhine-Westphalia, Germany. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore deny them.

THE PARTIES: DEFENDANTS

4. Admitted.

5. Defendants admit that Watson is registered as a Pharmacy Establishment in the State of New York and that it holds Registration Nos. 028681 and 028729 and state that the registrations speak for themselves. Otherwise denied.

6. Defendants admit that Andrx is a limited liability company organized and existing under the laws of the State of Delaware, and that it has a place of business at 4955 Orange Drive, Davie, FL 33314. Otherwise denied.

7. Defendants admit that Watson and Andrx are both subsidiaries of Andrx Corporation, which is a wholly-owned subsidiary of Actavis, Inc., which was formerly known as Watson Pharmaceuticals, Inc., and that Watson and Andrx have some employees, officers and directors in common. Defendants further state that the Watson and Andrx letters referred to in this paragraph speak for themselves. Otherwise denied.

JURISDICTION AND VENUE

8. Admitted.

9. This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants state that Watson will not contest personal jurisdiction

in this district for purposes of this case. Defendants admit that Watson did not contest personal jurisdiction in this Judicial District in *Purdue Pharma L.P. et al. v. Watson Laboratories, Inc. – Florida et al.*, C.A. No. 11-cv-2036 (SHS) (S.D.N.Y.) and *Purdue Pharma L.P. et al. v. Watson Laboratories, Inc. – Florida*, C.A. No. 12-cv-3111 (SHS) (S.D.N.Y.). Otherwise denied.

10. This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants state that Andrx will not contest personal jurisdiction in this district for purposes of this case. Defendants admit that Andrx did not contest personal jurisdiction in this Judicial District in *Purdue Pharma L.P. et al. v. Watson Laboratories, Inc. – Florida et al.*, C.A. No. 11-cv-2036 (SHS) (S.D.N.Y.). Otherwise denied.

11. This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants state that they will not contest venue in this district for purposes of this case. Otherwise denied.

THE PATENT IN SUIT

12. Defendants admit that U.S. Patent No. 8,309,060 ("the '060 patent") is titled "Abuse-Proofed Dosage Form" and states on its face an issue date of November 13, 2012. Defendants also admit that the '060 patent names Johannes Bartholomaus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić as inventors. Defendants further admit that the '060 patent is listed in the FDA's Orange Book in connection with OxyContin® 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg. Watson further admits that a copy of the '060 patent is attached to the complaint as Exhibit A. Otherwise denied.

DEFENDANTS' ANDAS

13. Defendants admit that Watson submitted Abbreviated New Drug Application ("ANDA") No. 202352 to the FDA and state that ANDA No. 202352 speaks for itself. Otherwise denied.

14. Defendants admit that in compliance with applicable laws and regulations, Watson's ANDA No. 202352 contains a Paragraph IV certification for the '060 patent and state that the Paragraph IV certification for the '060 patent speaks for itself. Otherwise denied.

15. Defendants admit that Andrx submitted ANDA No. 202372 to the FDA and state that ANDA No. 202372 speaks for itself. Otherwise denied.

16. Defendants admit that in compliance with applicable laws and regulations, Andrx's ANDA No. 202372 contains a Paragraph IV certification for the '060 patent and state that the Paragraph IV certification for the '060 patent speaks for itself. Otherwise denied.

17. Defendants admit that Watson and Andrx sent letters to provide information concerning the submission of their respective ANDAs and state that the letters were in compliance with applicable laws and regulations and speak for themselves. Otherwise denied.

PLAINTIFFS' CLAIM FOR RELIEF

18. Denied.

19. Denied.

20. Denied.

21. Denied.

22. Denied.

MISCELLANEOUS

Except as otherwise specifically admitted, qualified, or denied herein, all allegations of the Complaint are hereby denied.

PLAINTIFFS' PRAYER FOR JUDGMENT

Defendants deny that Plaintiffs are entitled to any of the relief set forth in their prayer for judgment.

DEFENSES

Without any admission as to burden of proof and expressly reserving their right to assert any additional defenses that discovery may reveal, Defendants state the following defenses:

FIRST DEFENSE

Plaintiffs have failed to state a claim upon which relief may be granted.

SECOND DEFENSE (NON-INFRINGEMENT)

Watson's submission of ANDA No. 202352 did not infringe any valid claim of the '060 patent. Watson's manufacture, use, offer for sale, sale, and/or importation of the oxycodone tablets that are the subject of ANDA No. 202352 does not infringe and will not infringe any valid claim of the '060 patent.

THIRD DEFENSE (NON-INFRINGEMENT)

Andrx's submission of ANDA No. 202372 did not infringe any valid claim of the '060 patent. Andrx's manufacture, use, offer for sale, sale, and/or importation of the oxycodone tablets that are the subject of ANDA No. 202372 does not infringe and will not infringe any valid claim of the '060 patent.

FOURTH DEFENSE (INVALIDITY)

The claims of the '060 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103, and 112.

COUNTERCLAIMS FOR AFFIRMATIVE RELIEF AGAINST PLAINTIFFS

Watson Laboratories, Inc. – Florida ("Watson") and Andrx Labs, LLC ("Andrx"), by way of counterclaim against Purdue Pharma L.P. ("Purdue") and Grünenthal GmbH ("Grünenthal"), allege as follow:

THE PARTIES

1. Watson is a Florida corporation with its principal place of business at 4955 Orange Drive, Davie, FL 33314.

2. Andrx is a limited liability company organized and existing under the laws of the State of Delaware, and has a place of business at 4955 Orange Drive, Davie, FL 33314.

3. Upon information and belief, Purdue is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

4. Upon information and belief, Grünenthal is a corporation organized and existing under the laws of Germany, having an address at 52078 Aachen, Zieglerstaβe 6, North Rhine-Westphalia, Germany.

BACKGROUND

5. Upon information and belief, Purdue is the holder of NDA No. 022272, which relates to controlled-release oxycodone hydrochloride tablets. Upon information and belief, Purdue sells its controlled-release oxycodone hydrochloride tablets under the trade name OxyContin. Upon information and belief, OxyContin tablets are indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

6. Upon information and belief, U.S. Patent No. 8,309,060 ("the '060 patent") was issued on or about November 13, 2012, and states on its face it was assigned to Grünenthal.

7. Upon information and belief, Purdue alleges that it holds certain exclusive rights to the ’060 patent.

8. Upon information and belief, the ’060 patent is listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* for OxyContin.

9. Watson submitted ANDA No. 202352 to the FDA seeking approval to make, use, and sell oxycodone hydrochloride extended release tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, as a generic version of the drug described in NDA No. 022272. ANDA No. 202352 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’060 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use or sale of the drug product described in Watson’s ANDA No. 202352.

10. Andrx submitted ANDA No. 202372 to the FDA seeking approval to make, use, and sell oxycodone hydrochloride extended release tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg, as a generic version of the drug described in NDA No. 022272. ANDA No. 202372 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’060 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use or sale of the drug product described in Andrx’s ANDA No. 202372.

11. Watson and Andrx sent notices of the certifications to Purdue and Grünenthal on or about December 20, 2012.

12. On or about February 1, 2013, Purdue and Grünenthal filed the present action alleging infringement of the ’060 patent as a result of receiving certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’060 patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use or sale of the drug products described in Watson’s ANDA No. 202352 and Andrx’s ANDA No. 202372.

JURISDICTION AND VENUE

13. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

14. This Court may declare the rights and other legal relations of the parties involved pursuant to 28 U.S.C. §§ 2201 and 2202 because this action is based on a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of Watson and Andrx's oxycodone hydrochloride extended release tablets, pursuant to ANDA Nos. 202352 and 202372, would not infringe the '060 patent and that the claims of the '060 patent are invalid.

15. Purdue and Grünenthal are subject to the personal jurisdiction of this Court because they initiated and are prosecuting this action, and because they, either directly or through agents, conduct substantial business, have regular and systematic contacts, and derive substantial revenue within this District.

16. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

17. As a consequence of the foregoing, there is an actual and justiciable controversy between Watson and Andrx, and Purdue and Grünenthal, as to whether the filing of Watson's ANDA No. 202352 and Andrx's ANDA No. 202372 infringes the '060 patent and whether the claims of the '060 patent are invalid.

FIRST COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '060 Patent)

18. Defendants repeat and incorporate herein by reference the allegations set forth in paragraphs 1 - 17 of their counterclaims.

19. The claims of the ’060 patent are invalid under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 102, 103 and 112.

SECOND COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the ’060 Patent)

20. Defendants repeat and incorporate herein by reference the allegations set forth in paragraphs 1 - 19 of their counterclaims.

21. Watson’s submission of ANDA No. 202352 did not infringe any valid and enforceable claim of the ’060 patent. Watson’s manufacture, use, sale, offer for sale and/or importation of the oxycodone tablets that are the subject of ANDA No. 202352 would not infringe any valid and enforceable claim of the ’060 patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the ’060 Patent)

22. Defendants repeat and incorporate herein by reference the allegations set forth in paragraphs 1 - 21 of their counterclaims.

23. Andrx’s submission of ANDA No. 202372 did not infringe any valid and enforceable claim of the ’060 patent. Andrx’s manufacture, use, sale, offer for sale and/or importation of the drug product that is the subject of ANDA No. 202372 would not infringe any valid and enforceable claim of the ’060 patent.

PRAYER FOR RELIEF

WHEREFORE, Watson and Andrx respectfully demand judgment:

A. Dismissing the complaint with prejudice

B. Declaring that Watson’s submission of its ANDA No. 202352 did not infringe any valid claim of the ’060 patent;

C. Declaring that Watson's manufacture, use, offer for sale, sale, and/or importation of the oxycodone tablets that are the subject of ANDA No. 202352 does not infringe and will not infringe any valid claim of the '060 patent;

D. Declaring that Andrx's submission of its ANDA No. 202372 did not infringe any valid claim of the '060 patent;

E. Declaring that Andrx's manufacture, use, offer for sale, sale, and/or importation of the oxycodone tablets that are the subject of ANDA No. 202372 does not infringe and will not infringe any valid claim of the '060 patent;

F. Declaring that the claims of the '060 patent are invalid;

G. Finding that this case is exceptional under 35 U.S.C. § 285;

H. Awarding attorneys' fees, expenses, and costs of suit; and

I. Awarding such other and further relief as may be appropriate.

Dated: March 1, 2013

By: *s/ Brian J. Robinson*

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